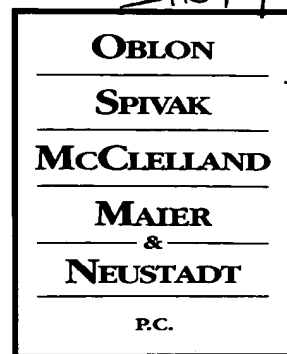




DOCKET NO.: 217689US40

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313



ATTORNEYS AT LAW

STEPHEN G. BAXTER  
(703) 413-3000  
SBAXTER@OBLON.COM

RE: Application Serial No.: 10/024,339

Applicants: Vincenzo CANNATA et al

Filing Date: December 21, 2001

For: STABLE GABAPENTIN COMPOSITIONS

Group Art Unit: 1614

Examiner: DELACROIX-MUIRHEID, C.

SIR:

Attached hereto for filing are the following papers:

**INFORMATION DISCLOSURE STATEMENT; STATEMENT OF INFORMATION AND RELEVANCY; FORM PTO-1449; CITED REFERENCES (6); COPY OF ZAMBON'S ANSWER TO TEVA'S COUNTERCLAIMS IN CIVIL CASE NO. 1:04-CV-1157 IN THE U.S. DISTRICT COURT FOR THE DISTRICT OF COLUMBIA; COPY OF REPLY, AFFIRMATIVE DEFENSES, COUNTERCLAIM AND JURY DEMAND OF COUNTER-DEFENDANTS APOTEX CORP. AND APOTEX INC. IN CIVIL ACTION NO. 1:04-CV-1157 IN THE U.S. DISTRICT COURT FOR THE DISTRICT OF COLUMBIA**

Our credit card payment form in the amount of **\$180.00** is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Richard D. Kelly

Registration No. 27,757

Stephen G. Baxter

Registration No. 32,884

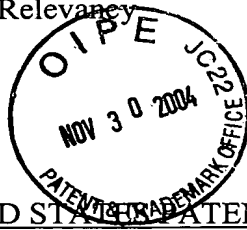
Customer Number

**22850**

(703) 413-3000 (phone)  
(703) 413-2220 (fax)

Application No. 10/024,339  
Statement of Information and Relevancy

DOCKET NO: 217689US40



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
VINCENZO CANNATA ET AL : EXAMINER: DELACROIX-MUIRHEID  
SERIAL NO: 10/024,339 :  
FILED: DECEMBER 21, 2001 : GROUP ART UNIT: 1614  
FOR: STABLE GABAPENTIN :  
COMPOSITIONS

STATEMENT OF INFORMATION AND RELEVANCY

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants respectfully request consideration of the following information and statement of relevancy for the references cited on the Form PTO 1449 submitted herewith.

Information:

U.S. Patent 6,531,509 ("the '509 patent") has already been made of record in the present application. The '509 patent is also the subject of patent litigation in the United States District Court for the District of Columbia. In this regard, Applicants are filing herewith copies of:

1. Zambon's Answer to Teva's Counterclaims in Civil Case No. 1:04-CV-1157 in the U.S. District Court for the District of Columbia ("the Zambon Answer"); and

~~12/01/2004 GWORDDF1 00000010 10024339~~

~~01-FC-1806~~

~~180.00 DP~~

2. Reply, Affirmative Defenses, Counterclaim and Jury Demand of Counter-Defendants Apotex Corp. and Apotex Inc. in Civil Action No. 1:04-CV-1157 in the U.S. District Court for the District of Columbia (“the Apotex Reply”).

In paragraphs 205-266 on pages 39-45 of the Apotex Reply, it is asserted that stable gabapentin containing more than 20 ppm of an anion of a mineral acid, such as chloride, was offered for sale and sold in the United States prior to June 15, 1999, by Plantex and Teva. At this time, the present Applicants have no factual knowledge with which to confirm or deny this assertion.

Statement of Relevancy:

1. U.S. Patent No. 4,960,931 (Butler et al) is discussed on pages 10-11 of the Zambon Answer.
2. U.S. Patent No. 6,054,482 (Augart et al) is discussed on page 11 of the Zambon Answer.
3. U.S. Patent No. 6,531,509 (Singer et al ‘509) is discussed throughout the Zambon Answer and throughout the Apotex Reply.
4. U.S. Patent Application Publication No. 2003/0055109 A1 (Singer et al ‘109) corresponds to U.S. Patent Application Serial No. 10/227,244, which is discussed on page 10 of the Zambon Answer and in paragraphs 154-204 on pages 34-39 of the Apotex Reply.
5. U.S. Patent Application Publication No. 2002/0045662 A1 (Singer et al ‘662) corresponds to U.S. Patent Application Serial No. 09/880,922, which is discussed on page 10 of the Zambon Answer and in paragraphs 154-204 on pages 34-39 of the Apotex Reply.

6. Published International Patent Application No. WO 98/28255 (Pesachovich et al)  
is discussed on page 10 of the Zambon Answer and in paragraphs 88-153 on pages  
25-33 of the Apotex Reply.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



---

Stephen G. Baxter  
Attorney of Record  
Registration No. 32,884

Customer Number  
**22850**

Tel: (703) 413-3000  
Fax: (703) 413-2220  
(OSMMN 08/03)

DOCKET NO. 217689US40

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Vincenzo CANNATA et al

SERIAL NO: 10/024,339

GROUP ART UNIT: 1614

FILED: December 21, 2001

EXAMINER: DELACROIX-MUIRHEID, C.

FOR: STABLE GABAPENTIN COMPOSITIONS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants wish to disclose the following information.

**REFERENCES**

- ☒ The Applicants wish to make of record the references listed on the attached Form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☒ A check or credit card payment form is attached in the amount required under 37 C.F.R. §1.17(p).

**RELATED CASES**

- ☐ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Customer Number

**22850**

Tel. (703) 413-3000  
Fax. (703) 413-2220  
(OSMMN 05/03)

Richard D. Kelly

Registration No. 27,757



Stephen G. Baxter

Registration No. 32,884

Form PTO 1449  
(Modified)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY DOCKET NO.

217689US40

SERIAL NO.

10/024,339

## LIST OF REFERENCES CITED BY APPLICANT

APPLICANT

Vincenzo CANNATA, et al.

FILING DATE

December 21, 2001

GROUP

1614

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	4,960,931	10/02/90	Donald E. Butler et al			
	AB	6,054,482	04/25/00	Helmut Augart et al			
	AC	6,531,509	03/11/03	Claude Singer et al			
	AD	2003/0055109 A1	03/20/03	Claude Singer et al			
	AE	2002/0045662 A1	04/18/02	Claude Singer et al			
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AO	WO 98/28255	07/02/98	WIPO		
	AP					
	AQ					
	AR					
	AS					
	AT					
	AU					
	AV					

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	
	AX	
	AY	
	AZ	

☐ Additional References sheet(s) attached

Examiner

Date Considered

\*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.